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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,077	09/30/2003	Mark S. Ortiz	END5100.0515145	9132

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EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/675,077	Applicant(s) ORTIZ, MARK S.	
	Examiner Natalie Pous	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/21/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because several characters are crossed out or scribbled through, making some of the characters difficult to read. For example, fig. 1, the distal hinge is inferred to be referenced by character 44, but that number is not clear in the drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 8, 9, 11, 12, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Huebsch et al. (US 5853422).

Regarding claim 1, Huebsch teaches an applier for an anastomosis ring device having proximal (14), center (18), and distal rings (16) connected respectively by proximal and distal hinged arms (22), the ring device having a generally cylindrical shape when unactuated (fig. 2) and a rivet shape when actuated (fig. 4), the applier comprising:

an elongate implement portion (40);

a handle connected to the implement portion (300);

an actuating member (122) internally engaged to a selected one of the rings of the anastomosis device; an arresting member (124) internally engaged to a selected second of the rings of the anastomosis device; and a control (312) coupled to the handle operably configured to cause movement of the actuating member (122), and thus the engaged ring (116), toward the arresting member (124), and thus the selected second ring, causing actuating the interposed hinged arms of the ring device (fig. 16).

Regarding Claim 2, Huebsch teaches the applier of claim 1, wherein the actuating member (122) is engaged to the distal ring (116).

Regarding Claim 3, Huebsch teaches the applier of claim 2, wherein the arresting member (124) is internally engaged to the proximal ring (114).

Regarding Claim 4, Huebsch teaches the applier of claim 3, further comprising a second control (310) coupled to the handle (300) and operably configured to cause distal movement of the arresting member toward the actuating member (Column 5, proximate lines 55-62).

Regarding Claim 5, Huebsch teaches the applier of claim 3, wherein the arresting (124) member engages the center ring (128), the applier further comprising:
a second actuating member (130) engaged to the proximal ring; and
a second control (310) coupled to the handle and operably configured to distally move the proximal ring toward the center ring (Column 5, proximate lines 55-62).

Regarding Claim 8, Huebsch teaches the applier of claim 1, wherein the actuating member distally terminates in a catch (132).

Regarding Claim 9, Huebsch teaches the applier of claim 8, wherein the actuating member includes a releasing surface (140) responsive to an actuated condition of the ring device to disengage the actuating member from the selected ring of the ring device (figs. 7 and 8).

Regarding Claim 11, Huebsch teaches the applier of claim 1, wherein the implement portion is dimensionally sized for endoscopic surgical use (fig. 5a).

Regarding Claim 12, Huebsch teaches an applier for an anastomotic ring device having a center circular portion longitudinally connected by a plurality of proximal arms (22) to a proximal ring (14) and by a plurality of distal arms (22) to a distal ring (16), the

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ring expanding each plurality of arms by compressing a respective ring toward the center circular portion (fig. 4), the applier comprising:

a first member (130) operative to internally engage and longitudinally move a selected one of a group consisting of the proximal ring, center circular portion, and distal ring; and a second member (132) operative to internally engage another one of the group to thereby mechanically ground for actuating at least one plurality of arms.

Regarding Claim 18, Huebsch teaches an applier for an anastomotic ring device having a center ring (18) longitudinally connected by a plurality of proximal arms (22) to a proximal ring (14) and by a plurality of distal arms (22) to a distal ring (16), the ring expanding each plurality of arms by compressing a respective ring toward the center circular portion, the applier comprising:

a means for inserting an unactuated anastomotic ring device to an anastomotic surgical site (fig. 5a); a means for inwardly compressing proximal and distal rings to actuate both plurality of arms (fig. 4).

Regarding Claim 19, Huebsch teaches the applier of claim 18, further comprising a means (300) for compressing one of a group consisting of the proximal and distal rings toward the center ring to actuate one interposed plurality of arms.

Regarding Claim 20, Huebsch teaches the applier of claim 18, further comprising a handle (300) means for independently actuating either plurality of arms (310, 312).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch in view of Adams (US 6632227). Huebsch teaches all elements of preceding dependent claims 1, 8 and 9 as previously described, wherein the applier includes a distal tip illuminator connected to the implement portion. Adams teaches an endoscopic device wherein the distal end comprises a light at the distal end in order to make visual observations of the desired site. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Huebsch with a light at the distal end as taught by Adams in order to make visual observations of the desired site.
6. Claims 6, 7 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch.

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Huebsch teaches all limitations of preceding dependent claims 1 and 12, but fails to disclose wherein the actuating member is engaged to the center ring to longitudinally move the second ring and further teaches the following:

wherein the applier further comprises a second actuating member (132) internally engaged to the distal ring of the ring device.

A releasable engagement mechanism responsive to an actuated condition of the anastomotic device (figs. 7 and 8)

handle (300) operably configured to position the first member.

A cannula (40) supporting the first and second members and operatively configured to distally receive the anastomotic device, dimensioned for endoscopic use (fig. 5a)

Huebsch does however teach wherein the actuating member is engaged to both the proximal and distal rings to actuate movement of both rings toward the center ring. It would have been an obvious matter of design choice to modify the device of Huebsch by attaching the actuator to the center ring as opposed to the proximal ring since the applicant has not disclosed that actuation by pulling center and distal rings toward the proximal ring is for any particular purpose or serves any advantage over pulling both rings toward the center ring and it appears that the device of Huebsch performs the task of actuating the device equally well as that disclosed in the application.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-

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6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP
5/16/06


(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER
5/30/06